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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,268	10/05/1999	BEHNAZ PARHAMI-SEREN	MGH-1526	9455

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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05/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/412,268

Applicant(s)

PARHAMI-SEREN ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 45-55 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 45-48 and 52-55 is/are allowed.
- 6) ☐ Claim(s) 49-51 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 5, 2007 is acknowledged and has been entered. Claims 1-44 and 56-60 have been canceled, claims 45-55 have been amended and new claim 61 has been added. An action on the RCE follows.

2. Claims 45-55 and 61 are pending and currently under examination.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 49-51 and 61 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lin et al, PNAS, ROC Part B: Life Sciences, 1998, 22: 129- 134, IDS item.

The claims are drawn to monoclonal antibodies having the same binding specificity as a monoclonal antibody produced by hybridoma deposited under ATCC accession number PTA-812, PTA 813, PTA 814, PTA 815 or an antigen binding fragment thereof, wherein the antibody has binding specificity for ouabain and for the ouabain component of a ouabain–carrier complex.

It is noted that the term “binding specificity” is not defined in the specification as originally filed and that the binding specificity of claims 49-51 is drawn to binding specificity for ouabain and for the ouabain component of a ouabain-carrier complex. Again, given that the term “binding specificity” is not defined in the specification as originally filed, given the teaching of the specification it is clear that the binding specificity of the antibody of claim 61 is also drawn to its binding specificity for ouabain and for the ouabain component of a ouabain-carrier complex, thus it appears that the binding specificity claimed is drawn to the ability of the antibody to detect analyte as opposed to nonanalyte, for example the ability to detect the ouabain portion rather than the carrier portion of a ouabain-carrier complex. Thus, the claims are broadly and reasonably read, for examination purposes, as being drawn to antibody with the same analytic binding specificity as the claimed specific antibodies, which as defined by Stites et al (Basic and Clinical Immunology, 7th Edition, 1976, Prentice Hall, London, p. 244) is “a vague term associated with the ability to detect analyte as opposed to nonanalyte.”

Lin et al teach the production of monoclonal antibody specific for ouabain using a ouabain-BSA construct (see p. 131) and further teaches that the monoclonal antibody produced binds to the ouabain as well as to the ouabain component of the ouabain-carrier complex as disclosed in Figure 1, Method II. The reference exemplifies the binding of the antibody to endogenous ouabain which does not comprise the carrier BSA construct (see Table 1). Thus the Lin et al monoclonal antibody has the same binding specificity as all of the claimed

antibodies in that it binds to ouabain and to the ouabain component of a ouabain-carrier complex. All of the limitations of the claims are met.

5. All other objections and rejections set forth in the previous office action are hereby withdrawn.

6. Claims 45-48, 52-55 are free of the art and allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
April 30, 2007

